

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number	09/971,774	
Filing Date	October 9, 2001	
First Named Inventor	REDMOND	
Group Art Unit	1623	
Examiner Name	Maier, Leigh C.	
Attorney Docket Number	1194-180	

Title: USE OF TAUROLIDINE AND/OR TAURULTAM FOR TREATMENT OF ABDOMINAL CANCER AND/OR FOR PREVENTION OF METASTASES

### REPLY BRIEF ON APPEAL UNDER 37 CFR § 1.193(b)(1)

Mail Stop - Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1540

Dear Sir:

This is a reply to the Examiner's Answer mailed January 21, 2005.

#### **Arguments**

1. Claims 1-5, 8, 9, 11, and 12 are non-obvious over Jacobi et al. in view of Monson et al.

The Examiner's answer sets forth that Appellants state that the prior art does not teach all the steps of the claimed method. According to the Examiner this passage in Applicants' argument addresses only Jacobi et al while the rejection is based on a combination of references. In addition, the Examiner asserts that Applicants allege that the combination of references does not teach the embodiment wherein taurolidine and/or taurultam is administered prior to forming a surgical opening.

According to the Examiner however, this embodiment was specifically addressed in the rejection.

In contrast to the Examiner's assertions, applicants reiterate that the Jacobi et al. reference merely discloses in vivo experiments in animals, according to the following steps of 1) introducing cancer cells intraperitoneally into each animal through abdominal incisions, 2) establishing pneumoperitoneum in each animal utilizing a gas, after introduction of the cancer cells, 3) introducing intraperitoneally a solution containing taurolidine, 4) closing abdominal incisions, and 5) excising later intraperitoneal tumors after the animals were sacrificed. Further, Monson et al. merely discloses the administration of taurolidine or taurultam by injection or infusion for the prevention of cancer metastases. Thus, Jacobi et al. and Monson et al. cannot be combined to suggest the specific sequence of steps of the present claims, wherein the tumor is removed, taurolidine and/or taurultam is administered to the abdomen prior to closing of the surgical opening and after surgical removal of the tumor, and additionally administering taurolidine and/or taurultam to the patient after closing the surgical opening.

Thus, the claimed invention in claims 1-5, 8, 9, 11, and 12 is unobvious over Jacobi et al. in view of Monson et al., as the Jacobi et al. reference does not teach or suggest the required steps in treating a patient with abdominal cancer according to the current invention as described above and combining Monson et al. with Jacobi et al does not cure this manifest defiency for the reasons set fort above. Applicants submit that, in contrast to the Examiner's assertions, Applicants' arguments specifically point out why the combination of the references is invalid and specifically points out which steps are not taught or suggested by this combination of references.

Applicants thus respectfully submit that the claims 1-5, 8, 9, 11, and 12 of the present

application are not obvious over Jacobi et al. in view of Monson et al., and applicants respectfully request withdrawal of this rejection.

# 2. Claims 1-12 are non-obvious over Jacobi et al in view of Monson et al and further in view of Allgood et al.

In the Examiner's answer she asserts that the Allgood et al references discusses typical methods known in the art. According to the Examiner Allgood et al discusses endoscopic surgery and is applied to the combination of prior art references for that reason. Further, in response to Applicants' argument that the Allgood et al disclosure includes a description of a sealing means in the trocar to prevent the flow of fluid, the Examiner asserts that the reference was used only for its general teaching regarding the use of trocars in endoscopic surgery.

The claims specify passing a solution containing taurolidine and/or taurultam through a trocar so as to contact internal tissue of the patient with the solution, which is in contrast to the disclosure in Allgood et al, which includes the description of a sealing means in the trocar to prevent the flow of fluid. Further, although Allgood et al. discusses endoscopic surgery, the reference cannot be combined with Jacobi et al. and Monson et al. to suggest the specific sequence of steps set forth in the claims, as outlined above.

Thus, the claimed invention in claims 1-12 is unobvious over Jacobi et al. in view of Monson et al. in further view of Allgood et al, as the Jacobi et al. reference does not teach or suggest the required steps in treating a patient with abdominal cancer according to the current invention as described above and combining Monson et al. and Allgood et al with Jacobi et al does not cure this manifest defiency for reasons set forth above.

Applicants thus respectfully submit that the claims 1-12 of the present application are not obvious over Jacobi et al. in view of Monson et al. in further view of Allgood et al, and applicants respectfully request withdrawal of this rejection.

### 3) Claims 1-5, 8, 9, 11, and 12 are non-obvious over Jacobi et al in view of Monson et al and further in view of Nicolson et al.

In the Examiner's answer, no further arguments were made by the Examiner other than a reference to the arguments discussed above. For the reasons above and the arguments submitted in the Appeal Brief Applicants submit that the claimed invention in claims 1-5, 8, 9, 11, and 12 is unobvious over Jacobi et al. in view of Monson et al. in further view of Nicholson et al, as the Jacobi et al. reference does not teach or suggest the required steps in treating a patient with abdominal cancer according to the current invention as described above and combining Monson et al. and Nicholson et al with Jacobi et al does not cure this manifest defiency for reasons set forth above.

Applicants thus respectfully submit that the claims 1-5, 8, 9, 11, and 12 of the present application are not obvious over Jacobi et al. in view of Monson et al. in further view of Nicholson et al, and applicants respectfully request withdrawal of this rejection.

## 4) Claims 1-5, 8, 9, 11, 12, and 26 are non-obvious over Jacobi et al in view of Monson et al and further in view of Physicians Desk Reference (PDR - 1995).

In the Examiner's answer, no further arguments were made by the Examiner other than a reference to the arguments discussed above. For the reasons above and the arguments submitted

in the Appeal Brief Applicants submit that the claimed invention in claims 1-5, 8, 9, 11, 12 and 26 is unobvious over Jacobi et al. in view of Monson et al. in further view of PDR-1995, as the Jacobi et al. reference does not teach or suggest the required steps in treating a patient with abdominal cancer according to the current invention as described above and combining Monson et al. and PDR-1995 with Jacobi et al does not cure this manifest defiency for reasons set forth above.

Applicants thus respectfully submit that the claims 1-5, 8, 9, 11, 12, and 26 of the present application are not obvious over Jacobi et al. in view of Monson et al. in further view of PDR-1995, and applicants respectfully request withdrawal of this rejection

### **CONCLUSION**

None of the applied references can be combined to suggest the specific steps of the present claims, wherein a tumor is removed, taurolidine and/or taurultam is administered to the abdomen prior to closing of the surgical opening and after surgical removal of the tumor, and additionally administering taurolidine and/or taurultam to the patient after closing the surgical opening. Thus, in view of the above, the claims of the current invention are non-obvious over Jacobi et al. in combination with the other applied art.

In view of the foregoing, Applicants respectfully submit that claims 1-12, and 26 are non-obvious over the cited prior art under 35 U.S.C. 103(a). All of the grounds for the rejections of claims 1-12, and 26 as advanced by the Examiner are submitted to be unsupportable by the record, and thus improper. The Honorable Board is therefore respectfully requested to reverse the final rejection, and to direct the passage of this application to issue.

RESPECTFULLY SUBMITTED,						
NAME AND	Willem F.C. de Weerd, Registration No. 51,613					
REG. NUMBER	1/1				/ 1	
SIGNATURE				DATE	3/21/05	
Address	Rothwell, Figg, Ernst & Manbeck 1425 K Street, N.W., Suite 800					
City	Washington	State	D.C.	Zip Code	20005	
Country	U.S.A.	Telephone	202-783-6040	Fax	202-783-6031	